IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Kleiman *et al.*	Atty Docket No.:	FLORA.1100
Serial No.:	09/899,432	Group Art Unit:	1617
Filed:	07/06/2001	Examiner:	Shobha Kantamneni

TITLE: **ANTIVIRAL COMPOSITION AND TREATMENT METHOD**

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class mail in an envelope addressed to " Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on:

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AFFIDAVIT
PURSUANT TO 37 C.F.R. §1.132

Assistant Commissioner of Patents
Alexandria, VA 22313-1450

Dear Assistant Commissioner:

STATE OF ARIZONA)

:

COUNTY OF MARICOPA)

I, David Ashley, being duly sworn, depose and say as follows:

I received a Bachelors of Science in Chemistry from Arizona State University in May of 1987. I have been employed by International Flora Technologies, Inc., (Technical Department) since 2003 where I serve as a chemist. Previously, I was employed at Safety-Kleen Systems, Inc., where I served as Compliance Manager from 2002-2003. I have also worked in various technical and managerial capacities at Onyx Environmental Services (Salesco Systems USA, Inc.), ADFlex Solutions Inc., and Revlon Consumer Products Corporation. I have over fourteen years of experience in analytical chemistry, environmental, health, and safety management. I am a Certified Hazardous Material Manager, and a member of the American Chemical Society.

I have undertaken an extensive review of United States Patent Application Serial No. 09/899,432 in conjunction with the Sintov *et al.* reference (WO 9602244 A1). The Sintov *et al.* reference is directed toward topical pharmaceutical compositions that include salts of fatty acids, specifically: linoleates, elaidates, palitates, myristates, oleates, malonates, succinates, adipates, pimelates, maleates, fumarates and azelates.

The invention referenced in Application Serial No. 09/899,432 is directed to methods for treating virus-induced and inflammatory diseases utilizing topical compositions that include monounsaturated long chain alcohols in combination with long chain fatty acid salts and fatty acid esters. More specifically, the salts of long chain fatty acids include fatty acids with chain lengths of 20 carbons or greater.

Salts of fatty acids are obtained through saponification of the fatty acids. It is general knowledge that solubility of fatty acid salts decreases with an increase in chain length of the fatty acids, and therefore chain length of fatty acids are a consideration in the manufacture of topical applications. *See* Exhibit 1, *excerpt from* Baileys Industrial Oil and Fat Products, 6th ed., vol. 6, page 106 (2005). The table in Exhibit 1 illustrates common fats and oils used in saponification of commercial products, and all of these fats and oils comprise carbon chain lengths of 18 carbons or less. Carbons with longer chain lengths than those illustrated in the table (*e.g.*, longer than C18) are "generally insoluble at room temperature".

The Sintov *et al.* reference follows this general knowledge in identifying "preferred" salts for "use in the present invention is a water-solubilized C_{16}-C_{18} carboxylic acid salt." *See* Sintov *et al.*, page 3, lines 1-2.

By contrast, the invention referenced in Application Serial No. 09/899,432 utilizes salts of fatty acids with carbon chain lengths of 20 carbons or greater in combination with monounsaturated alcohols and mixed esters for topical applications for treatment of viral infections and inflammatory diseases. The effect of the combination referenced in this invention is a dramatic increase in antiviral activity. This effect could not have been expected based on the general knowledge available because salts of fatty acids with carbon chain lengths of 20 carbons or greater would generally have been thought to hinder absorption due to their insolubility. In other words, a 100-fold increase in

antiviral activity is observed where the expectation would be that the delivery mechanism would not traffic the antiviral as effectively due to the decreased solubility associated with fatty acid salts having chain lengths of 20 carbons or greater.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful and false statements may jeopardize the validity of the subject patent application or any patent issued thereon.

I further declare that I have received no special compensation or consideration for making this affidavit, nor have I been in any way told, either directly or by implication or inference, by anyone that my employment by International Flora Technologies, Inc., or my professional advancement or other matters of personal or professional interest to me depend in any way on whether or not I make this affidavit or the content thereof. I further declare that I make this affidavit of my own free will and choice without any duress or influence of any kind, believing fully in the truth of the statements made by myself herein.

David Ashley

I, CAROL HYNES, a Notary Public in and for the County and State aforesaid, do hereby certify that David Ashley, whose name is subscribed to the foregoing instrument, appeared before me this day in person and acknowledge that he signed, sealed and delivered the said instrument as his free and voluntary act and deed for the uses and purposes therein set forth.

Given under my hand and Notary Seal this 25th day of MARCH 2008.

My commission expires on Nov. 29, 2011

SEAL

CAROL HYNES
Notary Public - Arizona
Maricopa County
My Comm. Expires Nov 29, 2011

BAILEY'S INDUSTRIAL OIL AND FAT PRODUCTS

Sixth Edition

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Industrial and Nonedible Products from Oils and Fats

Edited by

Fereidoon Shahidi

Memorial University of Newfoundland

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TABLE 1. Fatty Acid Compositions of Common Fats and Oils.[a]

Common Name	Chemical Name	Chemical Formula	Symbol	Animal Fats, %		Vegetable Oils, %		
				Tallow	Lard	Coconut	Palm kernel	Soybean
			Saturated Fatty Acids					
caprylic	octanoic	$C_8H_{16}O_2$	C 8			7	3	
capric	decanoic	$C_{10}H_{20}O_2$	C10			6	3	
lauric	dodecanoic	$C_{12}H_{24}O_2$	C12			50	50	0.5
myristic	tetradecanoic	$C_{14}H_{28}O_2$	C14	3	1.5	18	18	0.5
palmitic	hexadecanoic	$C_{16}H_{32}O_2$	C16	24	27	8.5	8	12
margaric	heptadecanoic	$C_{17}H_{34}O_2$	C17	1.5	0.5			
stearic	octadecanoic	$C_{18}H_{36}O_2$	C18	20	13.5	3	2	4
			Unsaturated Fatty Acids					
myristoleic	tetradecenoic	$C_{14}H_{26}O_2$	C14:1	1				
palmitoleic	hexadecenoic	$C_{16}H_{30}O_2$	C16:1	2.5	3			
oleic	octadecenoic	$C_{18}H_{34}O_2$	C18:1	43	43.5	6	14	25
linoleic	octadecadienic	$C_{18}H_{32}O_2$	C18:2	4	10.5	1	2	52
linolenic	octadecatrienic	$C_{18}H_{30}O_2$	C18:3	0.5	0.5	0.5		6

[a]From historical data and Procter & Gamble analyses.

are practical considerations that must be addressed when performing this reaction on a commercial scale.

Compositional differences in the fats and oils give rise to their significantly different physical properties and those of the resulting fatty acids and soaps. Fats and oils are triglycerides composed of glycerol ester linked to three fatty acids. The main compositional difference is the chain-length distribution of the fatty acids associated with the fats or oils. The compositions found in some commercially important fats and oils are summarized in Table 1. High levels of unsaturated (containing double bonds) or short-chain-length components produce fatty acids that are liquid and soaps that have high water solubilities at room temperature. Conversely, high levels of saturated, long-chain-length components produce waxy and hard fatty acids, e.g., candle wax, and soaps that are essentially insoluble at room temperature. Furthermore, unsaturated components are more susceptible to oxidative degradation, i.e., the oxidation of the double bond to form a number of shorter chain components. This gives rise to undesirable odors and darker colors. A key to producing soaps with acceptable qualities is the proper blending of these fats and oils.

The quality, i.e., level of impurities, of the fats and oils used in the manufacture of soap is important in the production of commercial products. Fats and oils are isolated from various animal and vegetable sources and contain different intrinsic impurities. These impurities may include hydrolysis products of the triglyceride, e.g., fatty acid and mono/diglycerides; proteinaceous materials and particulate dirt, e.g., bone meal; and various vitamins, pigments, phosphatides, and sterols.